US EPA ARCHIVE DOCUMENT

ABAMECTIN. 009

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MEMORANDUM

Subject: PP#1F03973 and 1H05611. Abamectin (Avermectin B_1) for Use in/on Almonds, Walnuts, and Head Lettuce. Registrant's Response to Conclusions/Deficiencies Outlined in Memo of G.J. Herndon Dated 11/26/91.

MRIDs# 427652-01 and 427652-02 (12 volumes).
DP Barcode# D191433.
CBTS# 11901.

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In a letter received by the Agency on 5/6/93, Merck Sharp and Dohme is responding to deficiencies cited in the memo of G.J. Herndon dated 11/26/91 concerning PP#1F03973 and 1H05611. The original petition, PP#1F03973/1H05611, involved tolerances on both head lettuce and tree nuts. With the current submission, the company has responded separately to the head lettuce and tree nut concerns. This review is in response to the **head lettuce** concerns; a separate memo addresses Merck's response to the tree nut

deficiencies (see memo of G.J. Herndon dated 5/19/94; DP Barcode D195880, CBTS# 12660).

With PP#1F03973/1H05611, Merck Sharp and Dohme is requesting the establishment of permanent tolerances for abamectin (avermectin B_1) insecticide/miticide and its delta-8,9-isomer in/on the following commodities:

Commodity	Tolerance (ppm)
Almonds	0.005
Walnuts	0.005
Head Lettuce	0.05
Almond Hulls	0.10

Technically, with the exception of the tolerances on fresh tomatoes and tomato pomace, all the tolerances established for avermectin B_1 (40 CFR 180.449, 185.300, and 186.300) have expired (expired on or before 3/31/93). The registrations have been extended and RD is in the process of extending the tolerances until 1997 (private conversation with George LaRocca/Adam Heyward on 5/10/94).

Conclusions and Recommendations

With the current submission, the registrant has satisfied the previous deficiencies associated with the **head lettuce portion only** of PP#1F03973 and 1H05611 (Use of abamectin in/on almonds, walnuts, and head lettuce). The other deficiencies concerning the other commodities associated with this petition are still outstanding, as noted in a concurrent memorandum (see memo of G.J. Herndon dated 5/19/94; DP Barcode D195880, CBTS# 12660)

Detailed Considerations

The Deficiencies listed below were cited by CBTS in the 11/26/91 memo of G.J. Herndon concerning PP#1F3973/1H5611. Responses were received from the registrant on 5/6/93 and are reviewed below.

Deficiency 7a.

No new storage stability studies were provided with this petition. The storage study data from previous submissions on citrus and tomatoes are not adequately representative of almond nuts, walnuts, almond hulls, and head lettuce, nor are they adequate in duration. Therefore, at a minimum, the registrant must provide all currently available storage stability data on any RAC that show that avermectin B_1a, avermectin B_1b, and the delta-8,9-isomer of avermectin B_1a are stable over a period of at least 26.5 months. Otherwise, the registrant must provide data to show that

avermectin B_1a, avermectin B_1b, and the delta-8,9-isomer of avermectin B_1a are stable in a representative leafy vegetable commodity (lettuce, celery, or spinach) over a period of 26.5 months and a representative tree nut commodity (almond, pecan, or English walnut) over a 14 month period. In addition, abamectin recoveries must be provided for almond hulls over a 23.5 month period.

Registrant's Response to Deficiency 7a.

The registrant has references additional storage stability data that have been generated other than the citrus and tomatoes referenced in the original memo. New crops include celery (24 months), pears (35 months), strawberries (24 months) and cottonseed (14 months). The composite crops/recoveries are shown in Table 1.

Table 1

Storage Stability Recoveries for Abamectin Residues in Various Crop Matrices (stored at ≤ -10°C)

Matrix	Length of Frozen Storage (months)	Fortification Level (ppm) and Compound	Method Recovery at Longest Time Interval#	Storage Stability Recovery at Longest Time Interval*
celery	24	0.010 - B1a	70%	79%
		0.206 - B1a		70%
		0.015 - B1b		87%
		0.010 - Δ8,9 isomer		70%
pears	35	0.010 - B1a	95%	84%
		0.071 - B1a		86%
		0.005 - B1b		72%
		0.010 - Δ8,9 isomer		94%
strawberries	24	0.010 - B1a	105%	98%
		0.071 - B1a		102%
		0.005 - B1b		109%
		0.010 - Δ8,9 isomer		94%
tomatoes	24	0.010 - B1a	87%	88%
		0.051 - B1a		86%
		0.004 - B1b		90%
		0.009 - Δ8,9 isomer		74%
cottonseed	14	0.010 - B1a	73%	58%
whole oranges	29	0.010 - B1a	86%	89%
		0.052 - B1a		89%
		0.004 - B1b		95%
		0.010 - Δ8,9 isomer		84%
whole grapefruit	29	0.010 -B1a	96%	92%
		0.052 - B1a		82%
		0.004 - B1b		104%
		0.010 - Δ8,9 isomer		85%
whole lemons	29	0.010 - B1a	84%	86%
		0.052 - B1a		86%
		0.004 - B1b		98%
		0.010 - Δ8,9 isomer		83%
orange peel	52	0.025 - B1a	87%	67%
grapefruit peel	47	0.005 - B1a	unk.	85%
		0.025 - B1a		70%
lemon peel	47	0.005 - B1a	88%	93%

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		0.025 - B1a		79%

- fresh fortification
* - uncorrected for method recovery

CBTS's Comments and Conclusions Concerning Deficiency 7a.

The additional data provided show that residues of avermectin are stable on frozen celery stored for up to 24 months. This data should be adequate to insure the stability of avermectin residues in the head lettuce samples (generated for the magnitude of the residue study) which were stored frozen for up to 26.5 months. **Deficiency 7a is resolved.**

Deficiency 7b.

The registrant made no mention of the conditions under which the samples were held during transit from the field to the lab. This time period was as long as 18 days in transit. CBTS would like the registrant to comment on whether the samples were kept frozen during this time.

Registrant's Response to Deficiency 7b.

The registrant provided additional dates, temperatures, and references that track the samples from all 11 field trial locations during shipping (MRID# 427652-01).

CBTS's Comments and Conclusions Concerning Deficiency 7b.

The additional data presented provide adequate evidence to show that the samples were stored frozen during transport. **Deficiency 7b is resolved.**

Deficiency 8.

The registrant made no mention about whether or not the outer leaves of the lettuce heads were removed before processing and extraction. CBTS would like the registrant to clarify this point.

Registrant's Response to Deficiency 8.

" The only leaves removed before processing and extraction were the leaves normally left in the field during commercial harvest. Merck protocols incorrectly referred to these leaves as "wrapper leaves", but the protocol did clarify that "for the purpose of the protocol, wrapper leaves are defined as those leaves that would normally be left in the field during commercial harvest of lettuce". The lettuce head assayed contained the leaves that would arrive at the grocery store and represent worst case for residues based on the leaves actually sprayed".

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CBTS's Comments and Conclusions Concerning Deficiency 8.

Deficiency 8 is resolved. In future field trials on any leafy vegetable, we suggest that protocols specify that only obviously decomposed or withered leaves be removed prior to analysis.

Deficiency 9.

Pending the results from the requested storage stability study (see Detailed Conclusions, Storage Stability), the proposed almond nut, almond hull, walnut, and head lettuce tolerances may not be adequate. A final decision on the appropriate tolerance levels will be made after the storage stability data are submitted.

Registrant's Response to Deficiency 9.

No response was necessary.

CBTS's Comments and Conclusions Concerning Deficiency 9.

The storage stability data show adequate stability of avermectin residues in various matrices, which cover treenuts and head lettuce. **Deficiency 9 is resolved.**

cc: PP#1F03973, RF, circu., E. Haeberer (section head),
G.J. Herndon.

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